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Division of UNIROYAL, Inc.Naugatuck, Connecticut
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September 12, 1975

Special SPI Meeting -- FDA PVC Proposal

This meeting was held on 9-10-75 and attended by about 100 interested industry people. Purpose was to review the FDA Proposal of 9-3-75 involving "Vinyl Chloride Polymers In Contact With Food". All written comments regarding the Proposal are due by 11-3-75.

SPI position will be to support the FDA proposed "safe" uses of PVC for thin film, gaskets, coatings, flexible tubing, etc. They will challenge the FDA position on restriction of "rigid and semi-rigid" articles. Sub-groups were formed to collect all available data which it is hoped will show no detectable VCM in food when low residual VCM polymers are used. SPI will make the point that a "hazardous substance" such as VCM is acceptable to make a food contact polymer (PVC) as long as none of the starting material can reasonably be expected to end up in a food product.

There was considerable discussion about levels of analytical sensitivity to prove "zero" VCM in food. FDA has available a method validated at 20 ppb. There are other methods claimed to be good down to 2 ppb. Most agreed that below 20 ppb it was very difficult to get accuracy.

✓ A report was given by the SPI VCM Toxicology Task Force. They have met with FDA regarding possible long range, low level, VCM feeding studies. FDA attitude strongly suggested that little would be gained - at least in the foreseeable future - by starting new toxicity tests. Additional metabolic work (Dow) will be pursued to clarify if VCM is a direct carcinogen or the toxicity results from metabolites which are formed above a certain unknown threshold concentration.

Regarding a request for a public hearing, SPI will not pursue too vigorously at the moment. Their position regarding a hearing may be determined by the technical information being amassed for their written input. Also, they may have to react to a possible public hearing request by those who feel the FDA Proposal is not restrictive enough.

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